

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kenneth A. Hill, Sr. et. al Art Unit : 3626
Serial No. : 09/996,100 Examiner : Vivek D. Koppikar
Filed : November 26, 2001 Conf. No. : 2510
Title : AUTOMATED SYSTEM AND METHOD FOR PROCESSING
PRESCRIPTIONS

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ARGUMENTS

This Pre-Appeal Brief is being filed pursuant to the Pre-Appeal Brief Conference Pilot Program. A Notice of Appeal accompanies this submission. This Pre-Appeal Brief is responsive to the final Office Action mailed March 23, 2007, in which all pending Claims 1-30 were rejected.

The Claims are allowable over *Feeney* and *Akers* even in view of the other cited art

The Office Action rejects every claim under 35 U.S.C. §103(a) relying, at least in part, on both U.S. Patent Application Publication No. 2002/0032582 to Feeney, Jr. *et al.* ("*Feeney*") and U.S. Patent Application Publication No. 2002/0169637 to Akers ("*Akers*").¹ Throughout prosecution, Applicants have made several attempts to correct misplaced assertions that these cited references teach or suggest particular limitations of the current claims, namely i) that the central fill inventory, which dispenses the prescription drugs, is remote from the pharmacy; and ii) that prescription drugs are dispensed from the central fill inventory via shipments. For example, both *Feeney* and *Akers* simply fail to teach that a pharmacy prescription processing subsystem creates "a queue of prescription requests from the received plurality of prescription requests, each prescription request in the queue eligible to be filled by a central fill inventory remote from the first pharmacy prescription processing subsystem." Both *Feeney* and *Akers* also fail to teach "dispensing a plurality of drugs from the central fill inventory via one or more

¹ While other references have been cited by the Office Action in combination with *Feeney* and *Akers*, these references fail to teach or suggest the discussed deficiencies of the Feeney-Akers combination. The other references are U.S. Patent No. 6,549,956 to Bass *et al.*; U.S. Patent Application Publication No. 2003/0093321 to Bodmer *et al.*; U.S. Patent Application Publication No. 2003/0093307 to Renz *et al.*; U.S. Patent Application Publication No. 2002/0052760 to Munoz *et al.*; PDXinc.com; U.S. Patent No. 6,049,787 to Takahashi *et al.*; and U.S. Patent Application Publication No. 2002/0038259 to Bergman.

shipments, the dispensed plurality of drugs associated with the plurality of filled prescription requests.” Put simply, whether viewed individually or in combination, these references fail to teach or suggest every limitation of the present claims.

With respect to *Feeney*, the reference clearly fails to teach or suggest a central inventory that is remote or associated with a third party. In contrast to Claim 1, *Feeney* repeatedly discloses that the asserted dispenser is located at the medical office and that it is the doctor or another authorized medical office user that dispenses the prescription medications. *See e.g.*, *Feeney* at ¶¶ 168, 175-78, 181-185, and 197. Additionally, ¶ 219 of *Feeney* indicates that the prescription is routed to a pharmacy when the dispenser at the medical office is out of the particular medicine or when the patient prefers to not receive medicine at the medical office. Clearly, this medical office does not refer to a “central fill inventory” as recited in the present claims; it instead relies solely on local pharmacy inventories of the sort described, for example, in ¶ 7 of the present Application.² Importantly, ¶ 271 of *Feeney*, as previously cited by the Examiner, is part of the Over-the-Counter (OTC) Medications and Cosmeceutical discussion. *Feeney* at ¶ 269. In other words, ¶ 271 explicitly involves drugs that are over the counter – drugs that are not based on prescriptions – in direct contrast to the present claims.³ In short, ¶ 271 involves non-prescription medications dispensed at various points at the medical office by office staff, thus failing to teach or suggest a central fill inventory remote from the prescription provider.

In addition to the lack of a remote central fill inventory, *Feeney* contains no indication that the patient, pharmacy, or any other potential provider dispenses (prescription) drugs “via one or more shipments,” as recited in the present claims, where the dispensed drugs are based on prescriptions. For example, *Feeney* discusses its view of “[c]urrent prescription filling methods” in ¶ 6, which merely discloses a patient receiving his drugs and counseling from a local pharmacy inventory.⁴ In fact, *Feeney*’s “system overview” describes the present system as one “dispensing medication and information at the point-of-service while incorporating data

² Indeed, Claim 19 of the present Application recites both “a local inventory” and “a central fill inventory.”

³ This section actually indicates that the OTC subsystem assists “the physician office staff” to perform tasks such as “dispensing OTC medications from a number of office locations.” *Feeney*, ¶¶ 270, 271.

⁴ While it characterizes such methods as inadequate and inefficient, *Feeney*’s solution is to control this dispensing method using dispensers (typically – if not always – at medical offices) “configured to controllably release a product in response to a control signal.” *Feeney*, ¶25; *see id.*, ¶¶ 30, 33, 35, 38, 40, 41, 42, and 46.

management into the dispensing process.” *Id.*, ¶¶ 168, 167 (emphasis added). Accordingly, *Feeney*’s controlled dispensing methods fail to teach, suggest, or disclose “dispensing a plurality of drugs from the central fill inventory via one or more shipments, the dispensed plurality of drugs associated with the plurality of filled prescription requests” as recited in Claim 1.

While the latest Office Action admits *Feeney*’s deficiencies, the Office Action now asserts that those deficiencies are overcome by *Akers*. Wrong. For example, *Akers* fails to teach or suggest “a central fill inventory which is remote from the first pharmacy prescription processing subsystem and dispensing a plurality of drugs from the central fill inventory via one or more shipments.” *Present Office Action*, pgs. 3-4. Specifically, the Office Action relies on the so-called “remote location” from ¶ 95 of *Akers* to reject “each prescription request in the queue eligible to be filled by a central fill inventory remote from the first pharmacy prescription processing subsystem.” In response, Applicants assert that the Office Action fails to read ¶ 95 of *Akers* within the context of the rest of FIGURE 8. Put simply, the Office Action asserts that *Akers*’ remote location can act as the claimed central inventory – remote from the pharmacy – that dispenses “a plurality of drugs ... via one or more shipments, the dispensed plurality of drugs associated with the plurality of filled prescription requests.” But in direct contrast, *Akers* teaches that its so-called remote location **is the pharmacy**.

More specifically, *Akers* discloses that the asserted remote location is a telepharmacy that receives pre-packaged medicines for use in pharmacy services,⁵ which run counter to the Office Action’s assertions. First, the Office Action asserts that “it would have been obvious for one of ordinary skill in the art to have modified the combined teachings of *Feeney* in view of *Bass* with the aforementioned teachings from *Akers* [paragraph 95] with the motivation of having an enhanced means of storing pharmaceuticals as they are ordered (as they are needed) as recited in *Akers* (Section [0095]).” *Present Office Action*, pg. 4. Without support, the Office Action attempts to explain “shipping” from *Akers*’ remote location: “Note: The Examiner takes the position that the ‘**remote location**’ in *Akers* is run by a wholesaler who operates or manages the warehouse where the pharmaceuticals are stored.” *Id.* at pg. 8 (emphasis added). But this

⁵ For example, *Akers* (at FIGURE 8 and method 800) teaches that the prescriptions are pre-packaged into dosages at step 802, which are then transferred to – not from – the remote location at step 806 for subsequent dispensing. Thus, while they may be sent to the remote location because of low inventory, the pre-packaged medicines include predetermined dosages and are only later matched up to a patient’s prescription request.

position is in direct contrast to *Akers*' text, which states that the remote location acts as the pharmacy or some other location providing telepharmacy services.⁶ Clearly, if the remote location in *Akers* is the telepharmacy, it is not "a central fill inventory ... remote from the first pharmacy prescription processing subsystem" as recited in Claim 1. Accordingly, the remote location in *Akers* cannot be the asserted central fill inventory because it is the pharmacy and there is no indication that the pre-packager of the medicines processes prescription requests.

In an effort to further clarify this rejection, the Office Action adds another note: "*Akers* does not explicitly state that the pharmaceutical packages are shipped from the remote inventory site to the pharmacy or provider however [*sic*] this is a business practice well known in the pharmaceutical and health care industry and at the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the combined system of *Feeney* in view of *Bass* and *Akers* with the aforementioned business practice with the motivation of providing a means so that a pharmacy (provider) could provide a patient with counseling before the patient received their medication in case the remote counseling data taught in *Akers* was not available." *Id.* at pg 8. As shown above, the Office Action is correct that *Akers* "does not explicitly state that the pharmaceutical packages are shipped from the remote inventory site to the pharmacy" because *Akers* states that the remote location is the telepharmacy. Yet on the next page, the Office Action states that it would have been "obvious" to combine *Feeney-Bass* with *Akers* with the motivation of "having an enhanced means of storing pharmaceuticals and packaging and shipping them to the pharmacies as they are ordered (as they are needed) as recited in *Akers* (Section [0095])." *Id.* at pg. 10 (emphasis added). In contrast to this new position, the Office Action admitted that *Akers* does not recite such shipments just pages before. Thus, this asserted motivation runs counter to the reference and the Office Action's prior statements.

Moreover, *Feeney* and *Akers* are directed at different technologies, with no suggestion or motivation to combine beyond the Office Action's incorrect assertions. *Feeney*'s professed "invention is generally directed to systems and methods for medical product dispensing and integrated information distribution and business management [and] relates to a medical system

⁶ "The remote site can be a facility that does not have a licensed practitioner onsite but which has personnel that have been trained to operate telepharmacy equipment or other suitable equipment." *Akers*, ¶ 0092.

for integrating data management with the process of controllably dispensing products including medications” (*Feeney*, ¶¶ 25), while *Akers* recites “a system and method for electronic medical file management . . . that overcome known problems with managing electronic medical files [and, in particular], a system and method for electronic medical file management . . . that provide[s] for electronic medical file integrity and continuity, so as to prevent electronic medical files from being misfiled or tampered with” (*Akers*, ¶¶ 6-7). Even if a suggestion or motivation to combine exists, *Feeney* specifically teaches away from such a combination.⁷

In short, the Office Action admits that *Feeney* fails to show a central fill inventory that is remote from the pharmacy and dispenses drugs via shipments and there is no teaching, suggestion, or disclosure in *Akers* to satisfy *Feeney*’s deficiencies. For at least these reasons, Applicant submits that *Feeney*, *Akers*, or a combination thereof, fails to teach, suggest, or disclose – indeed seems to teach against – certain aspects of the present claims. The other art cited in the rejections fail to account for the deficiencies of *Feeney*. Accordingly, Applicants request reconsideration and allowance of Claims 1-30.

CONCLUSION

For the reasons above, Appellants respectfully submit that the present claims are allowable over the cited prior art references. Reversal of the rejections under 35 U.S.C. §§ 103(a) is respectfully requested. If questions remain, please contact the undersigned.

The Appeal fee in the amount of \$250 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization to Deposit Account No. 06-1050. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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⁷ For example, *Feeney* repeatedly discusses the dispenser in terms of the doctor’s office. *See infra*.